DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

NOV 22 1999

R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology
Consumer Healthcare Products Association
1150 Connecticut Avenue, N.W.
Washington, D.C. 20036-4193

Dear Dr. Soller:

I am writing to inform you that earlier today the agency posted on the Internet a draft guidance for industry entitled "Labeling OTC Human Drug Products Using a Column Format." The draft guidance may be found at http://www.fda.gov/cder/guidance/index.htm.

This Level 1 draft guidance is being issued consistent with the agency's good guidance practices (62 FR 8961, February 27, 1997). A notice announcing the availability of this draft guidance will appear in the Federal Register in the near future. Written comments may then be submitted for 60 days.

The approach for Level 1 guidances is to issue them as a draft, not for implementation. The draft guidance represents the agency's current thinking on using a column format in the labeling of OTC human drug products consistent with the existing regulations. Your association members can now start preparing labeling using this format.

Please inform your association members about the availability of this draft guidance. You and your members will want to prepare some draft labeling using this guidance and then submit comments within the comment period. It is our plan to prepare a final guidance as soon as possible after the comment period ends.

We hope this information is helpful.

Sincerely yours,

Charles J. Ganley, M.D.
Director
Division of Over-the Counter Drug Products
Center for Drug Evaluation and Research

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